IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BONE CARE INTERNATIONAL L.L.C. and GENZYME CORPORATION, Plaintiffs, v. ANCHEN PHARMACEUTICALS, INC., Defendants.	C.A. No. 10-cv-512 (GMS) C.A. No. 09-cv-285 (GMS) (Consolidated)

ORDER

WHEREAS, on June 10, 2010, Genzyme Corporation and Bone Care International, LLC (collectively, "Genzyme") filed a complaint (D.I. 1) against Anchen Pharmaceuticals, Inc. and Anchen Incorporated (collectively, "Achen"), alleging that Anchen infringed its U.S. Patent No. 5,602,116 (the "'116 Patent");

WHEREAS, on August 20, 2010, Achen filed its Answer to Genzyme's complaint (D.I. 8), raising, among other defenses, a counterclaim in Count V seeking judicial declaration that U.S. Patent No. 6,903,083 (the "'083 Patent") is unenforceable (id. at ¶¶ 72-75);

WHEREAS, on August 20, 2010, Anchen filed a Motion for Judgment on the Pleadings on Count V of its counterclaims (D.I. 17), asserting that, pursuant to Federal Rule of Civil Procedure 12(c), its Count V counterclaim should be decided on the pleadings because Bone Care's action of disclaiming and requesting the delisting of the '083 Patent from the Orange Book renders this patent unenforceable as a matter of law, as such action statutorily disclaims all patent claims (D.I. 18);

WHEREAS, on October 12, 2010, Genzyme filed its Answer to Anchen's Answer to its Complaint (D.I. 16), wherein Genzyme acknowledged that Bone Care filed a Disclaimer in

Patent under 37 C.F.R. § 1.321(a) with the U.S. Patent and Trademark Office (the "PTO") on August 3, 2009 in connection with the '083 Patent (id. at ¶ 74);

WHEREAS Anchen, in its Brief in support of its 12(c) motion for judgment on the pleadings as to its Count V counterclaim, asserts that judgment is appropriate because it is well-settled that a "statutory disclaimer has the effect of cancelling the patent claims, meaning they cannot be reissued or subsequently enforced"[1];

WHEREAS Genzyme, in Response to Anchen's instant motion, argues that the court lacks subject matter jurisdiction to decide Anchen's declaratory judgment counterclaims because: (1) Bone Care statutorily disclaimed the '083 Patent and requested to "remove it from the U.S. Food and Drug Administration's [(the "FDA's")] Orange Book" (D.I. 20 at 2); and (2) Genzyme has covenanted not to sue Anchen for infringement of the '083 Patent, such that there is no injury-in-fact (id.)[2];

WHEREAS the court concludes, notwithstanding Genzyme's failure to address its subject matter jurisdiction argument in a motion to dismiss, that it possesses subject matter jurisdiction over Anchen's Count V counterclaim because, in light of the following, Genzyme's alleged actions constitute injury-in-fact: (1) in *Teva Pharmaceuticals U.S.A., Inc. v. Sebelius* the D.C. Circuit Court of Appeals clarified that the operative statutory scheme requires the "de-list" rule be interpreted so that the FDA can no longer apply the rule to effectuate a forfeiture of the

[1] *See, e.g., Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (quoting *Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935) ("Upon filing of the disclaimers, the original claims were withdrawn from the protection of the patent laws, and the public was entitled to manufacture and use the device originally claimed as freely as though it had been abandoned.")); *id.* at 1422 ("A statutory disclaimer under 35 U.S.C. § 253 has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the patent.").

[2] Genzyme notes in its Response that its arguments are consistent with this court's holding in *Bone Care Int'l LLC et al. v. Sandoz, Inc.*, C.A. 09-285 (consolidated), where it granted, on September 30, 2010, Bone Care's Motion to Dismiss Sandoz's declaratory judgment counterclaims with respect to the '083 Patent. Since that decision, however, the court granted Sandoz's Motion for Reconsideration of that dismissal, pursuant to the D.C. Circuit's holding in *Teva Pharms. U.S.A., Inc. v. Sebelius*, which clarified the implications of the FDA's "de-list" rule. *See id.* D.I. 39. Consequently, the court's original decision and rationale to which Genzyme cites has since been amended to reflect the change in the "de-list" rule law. *See infra* note 3.

first-filer's exclusivity[3]; and (2) in *Caraco Pharmaceutical Laboratories v. Forest Labs* the Federal Circuit concluded that a covenant not to sue does not remove declaratory judgment jurisdiction when a party has patents listed in the Orange Book because non-first filers still encounter delayed approval of their ANDAs despite such covenants[4];

WHEREAS "[j]udgment on the pleadings should be granted only if it is clearly established that no material issue of fact remains to be resolved and that the movant is entitled to judgment as a matter of law"[5];

WHEREAS, pursuant to Federal Rule of Civil Procedure 54(b), a court may direct entry of final judgment as to one or more, but "fewer than all, claims or parties . . . if the court expressly determines that there is no just reason for delay"[6];

WHEREAS, in determining whether judgment on the pleadings is appropriate pursuant to Rule 54(b), the court should determine whether: (1) a final decision on a cognizable/individual claim for relief is present; and (2) whether there is no just reason for delay[7];

WHEREAS the court concludes that both elements are present in the instant case[8] and no material issues of fact exist with respect to this issue[9];

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[3] *See Teva Pharms. U.S.A., Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010) ("We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve.").

[4] *See Caraco Pharms. Labs. v. Forest Labs*, 527 F.3d 1278, 1290-97 (Fed. Cir. 2008).

[5] *See Rodriguez v. Stevenson*, 243 F. Supp. 2d 58, 62 (D. Del. 2002) (citing *Travelers Indem. Co. v. Stedman*, 895 F. Supp. 742, 745-46 (E.D. Pa. 1995)).

[6] *See* Fed. R. Civ. P. 54(b).

[7] *See E.I. Du Pont Nemours v. Phillips Petroleum*, 720 F. Supp. 373, 387 (D. Del. 1989).

[8] Specifically, and as Anchen identifies in its opening brief in support of the instant motion: (1) Count V is a "cognizable/individual counterclaim for discrete relief as to the '083 patent"; and (2) "Genzyme has no[t presented a] defense to its own statutory disclaimer" and there is nothing indicating that granting Anchen's motion will result in a waste of judicial resources or impede judicial efficiency. (D.I. 18 at 10.) (citing *E.I. DuPont Nemours*, 720 F. Supp. at 382 (discussing factors courts should consider in determining whether to grant a judgment on the pleadings).

[9] As Anchen correctly notes in its Reply, Genzyme, in both its Answer to Anchen's Answer to the Complaint and its Opposition Brief to Anchen's Motion, admit that Bone Care has filed a Disclaimer in Patent under 37 C.F.R. § 1.321(a) with the PTO such that all of ' 083 claims have been disclaimed. (D.I. 16 at ¶ 74; D.I. 20 at 2.)

IT IS HEREBY ORDERED that:

1. Anchen's Motion for Judgment on the Pleadings on Count V of Its Counterclaims (D.I. 17) is GRANTED;
2. Achen's Request for Oral Argument (D.I. 22) in connection with this motion is DISMISSED as MOOT;
3. The Clerk of Court is directed to enter a final judgment for Anchen on Count V of Anchen's counterclaims pursuant to Federal Rule of Civil Procedure 54(b).

Dated: October 31, 2011

CHIEF, UNITED STATES DISTRICT JUDGE